REMARKS

Claims 15-16 and 18-37 constitute the pending claims in the present application. Claims 1-14 and 17 have been canceled without prejudice as being drawn to a non-elected invention. The Applicants expressly reserve the right to prosecute the canceled claims in one or more divisional applications claiming the benefit of priority to the instant application and its predecessor(s). 35 USC § 121.

Claims 18, 19, 31 and 33 have been amended. Amendment of the originally filed claims should in no way be construed as an acquiescence, narrowing, or surrender of any subject matter. The amendments are being made not only to point out with particularity and to claim the present invention, but also to expedite prosecution of the present application. Applicants reserve the option to prosecute further the originally filed claims or similar ones, in the instant or a subsequent patent application.

No new matter has been introduced by these amendments. Support for the amendments may be found throughout the specification and claims as originally filed.

For example, support for the term "menopausal status" may be found in the claims as originally filed.

Further, support for the terms "a member of the gonadotropin family" and "a form of said gonadotropin family member" may be found, for example, page 5, lines 13-33.

Applicants thank Examiner for indicating the allowability of claims 15 and 16 and for withdrawing several of the rejections from the previous Office Action.

Claim Objections

Claim 22

The Examiner has objected to claim 22 as being of improper dependent form because it allegedly fails to further limit claim 21. Specifically, the Examiner alleges that "both antibody pairs of claim 21 would detect total FSH as they bind to the alpha and beta peptides in an assay that requires both antibodies for carrying out the assay" and that "to have an antibody pair that binds both the alpha and beta peptide chains and not a differentiating

carbohydrate epitope or mutant form of FSH would detect total FSH". Therefore, the Examiner maintains that claim 22, which requires that the first antibody pair detect total FSH, does not serve to further limit claim 21.

Applicants urge that the Examiner is importing limitations into claim 21 that are not present in claim 21. Inferential limitations may not be added to a claim. See Ex parte Papst-Motoren, supra, citing In re Priest, 582 F.2d 33, 199 USPQ 11 (CCPA 1978). As the Federal Circuit stated in E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433, 7 U.S.P.Q.2d 1129, 1131 (Fed.Cir.1988), cert. denied, 109 S.Ct. 542 (1988):

> It is entirely proper to use the specification to interpret what the Patentee meant by a word or phrase in the claim. But this is not to be confused with adding an extraneous limitation appearing in the specification, which is improper. By "extraneous," we mean a limitation read into a claim from the specification wholly apart from any need to interpret what the patentee meant by a particular words or phrases in the claim. Where a specification does not require a limitation, that limitation should not be read from the specification into the claims. [citations omitted]

The Examiner is improperly reading the limitation "directing" in claim 21 to include the limitation "binding" or to be synonymous with the limitation "binding." However, "directing" means simply that the antibodies were raised against the combined alpha and beta chains and have the *potential* to "bind" in some fashion to the combined alpha and beta chains. It is well-known in the art that antibodies raised or "directed" against the same antigen may in practice "bind" the antigen in different ways (i.e., with different specificities), especially if the antigen is somehow modified, because the antibodies may recognize different regions of the same antigen. Indeed, the application discloses two different specific antibodies that were each raised or "directed" against the combination of alpha and beta chains, but have different binding specificities. Thus, the limitation that the antibody pairs are "directed" to the combined alpha and beta chains does not require that both antibody pairs would "bind" to the combined alpha and beta chains in the same way, particularly if the antibodies were mixed with various isoforms of the combined alpha and beta chains (i.e.,

modified forms of the original antigens against which they were raised). Hence, the Examiner is reading a limitation into claim 21 that is not present in the claim as written.

Claim 22 requires that the first antibody pair "detect" total FSH. To "detect" means that the antibody pair can "bind" total FSH. Because, as noted above, it is possible for two different antibody pairs to be both raised or "directed" against the combination of alpha and beta chains but "bind" the combination of alpha and beta chains with different specificities, claim 22 serves to further limit claim 21 by requiring that the first antibody pair be specific for, i.e. able to "detect" or bind to, total FSH. Accordingly, claim 22 serves to further limit claim 21.

Therefore, the Applicants respectfully request withdrawal of the objection to claim 22.

Claims 31-32

The Examiner has objected to claims 31-32 because the claims recite the phrase "configured such that the such that when." Applicants have amended claims 31-32 to remove the extra transitional phrase. Therefore, the Applicants respectfully request withdrawal of the objection to claims 31-32.

Claim Rejection – 35 U.S.C. §102(b) over O'Daly, et al. (U.S. Pat. No. 5,391,272)

The Examiner has rejected claims 18-20 and 33-37 under 35 U.S.C. §102(b) as allegedly anticipated by O'Daly, et al. (U.S. Pat. No. 5,391,272). The Examiner alleges that the instantly claimed methods and devices require assaying two different gonadotropins, as taught in O'Daly, et al.

Applicants urge that the Examiner is importing limitations into claims 18-20 and 33-37 that are not present in those claims. As discussed above, inferential limitations may not be added to a claim. The Examiner is improperly reading the term "different forms", which is explicitly used on page 5, lines 24 to 33, to refer to different isoforms of a particular member of the gonadotropin family, i.e., different glycosylation or charged or conformational states of FSH, as meaning or including "different members of the gonadotropin family," which is used to refer to different *members* of the gonadotropin family such as hCG, LH, FSH and TSH on page 5, lines 13-20. One of skill in the art would readily recognize and understand that a

given gonadotropin family member, distinguishable by its beta chain sequence from all other gonadotropin family members, could exist in a variety of glycosylated, charged, conformational, etc. forms. One of skill in the art would also readily recognize that various antibodies could distinguish among different forms of a particular gonadotropin family member. Claims 18 and 33, which have been amended to even further clarify this point, and their dependent claims, do not and did not prior to amendment include any language that includes assaying two different *members* of the gonadotropin family. Rather, the claims are drawn to assays that detect two different *forms* of one member of the gonadotropin family.

As discussed in Applicants' response of December 3, 2004, O'Daly does not disclose each and every element of the claimed invention. O'Daly teaches assays for detecting two different *members* of the gonadotropin family, FSH and LH. Applicants' claimed invention is drawn to assays for detecting two different *forms* of a given member of the gonadotropin family, i.e. different glycosylation or charged or other states of FSH *or* LH *or* other gonadotropin family member, not two different gonadotropin family members. Further, it is clear from the plain language of the specification supporting such claims that the disclosed methods and devices are used to determine differences in the forms of *individual* gonadotropin that exist in an individual as a consequence of her menopausal state. Accordingly, each and every element of the claimed invention is not taught or suggested by O'Daly.

Therefore, the Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b) over O'Daly, et al. (U.S. Pat. No. 5,391,272).

Claim Rejection – 35 U.S.C. §102(b) over Overlie, I, et al.

The Examiner has rejected has rejected claims 18-20, 26-29 and 33-37 under 35 U.S.C. §102(b) as allegedly anticipated by Overlie, I, et al (1999). The Examiner alleges that the instantly claimed methods and devices require assaying two different gonadotropins as taught in Overlie I.

As discussed above in Applicants' traversal of the rejection over O'Daly, claims 18 and 33 and their dependent claims, do not and did not prior to amendment include any language that includes assaying two different *members* of the gonadotropin family. Rather,

the claims are drawn to assays that detect two different *forms* of *one member* of the gonadotropin family.

As discussed in Applicants' response of December 3, 2004, Overlie I does not disclose each and every element of the claimed invention. Overlie I does not teach or suggest a pair of tests for the different forms of a gonadotropin family member; rather, the Examiner herself has pointed out that it teaches a test for the ratio of FSH/LH, two different gonadotropin family members. Accordingly, each and every element of the claimed invention is not taught or suggested by Overlie I.

Therefore, the Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b) over Overlie, I, et al (1999).

Claim Rejection – 35 U.S.C. §102(e) over Birken, et al. (U.S. Pat. No. 6,521,416).

The Examiner has rejected has rejected claims 18 and 26-30 under 35 U.S.C. §102(e) as allegedly anticipated by Birken, et al. (U.S. Pat. No. 6,521,416). The Examiner alleges that the instantly claimed methods and devices require assaying two different gonadotropins, as taught in Birken.

As discussed above in Applicants' traversal of the rejection over O'Daly, claim 18, and its dependent claims do not and did not prior to amendment include any language that includes assaying two different *members* of the gonadotropin family. Rather, the claims are drawn to assays that detect two different *forms* of *one member* of the gonadotropin family.

As discussed in Applicants' response of December 3, 2004, Birken does not disclose each and every element of the claimed invention. Birken does not teach or suggest a pair of tests for the different forms of a single gonadotropin family member. Rather, it simply provides a collection of unassociated assays and does not teach or suggest using the assays as claimed in combination for the determination of menopausal status. Accordingly, each and every element of the claimed invention is not taught or suggested by Birken.

Therefore, the Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(e) over Birken, et al. (U.S. Pat. No. 6,521,416).

Claim Rejection – 35 U.S.C. §102(b) over Niccoli, et al

The Examiner has rejected has rejected claims 18 and 26-27 under 35 U.S.C. §102(b) as allegedly anticipated by Niccoli, et al. (1996) as evidenced by Costagliola (1994). The Examiner alleges that the instantly claimed methods and devices require assaying two different gonadotropins, as taught in Niccoli.

As discussed above in Applicants' traversal of the rejection over O'Daly, claim 18, which has been amended to clarify this point, and its dependent claims do not and did not prior to amendment include any language that includes assaying two different *members* of the gonadotropin family. Rather, the claims are drawn to assays that detect two different *forms* of one member of the gonadotropin family.

As discussed in Applicants' response of December 3, 2004, Niccoli does not disclose each and every element of the claimed invention. Niccoli does not teach or suggest a pair of tests for the different forms of a gonadotropin family member. Rather, it simply provides a collection of unassociated assays and does not teach or suggest using the assays as claimed in combination for the determination of menopausal status. Accordingly, each and every element of the claimed invention is not taught or suggested by Niccoli.

Therefore, the Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(e) over Niccoli, et al. (1996).

Claim Rejection – 35 U.S.C. §112¶2 - Indefiniteness

The Examiner has rejected has rejected claims 31-32 under 35 U.S.C. §112¶2 as indefinite because the term "give rise to a similar indication" is allegedly not defined by the claims and the specification allegedly does not provide a standard for ascertaining the "requisite degree" of similarity the indications must have to be considered similar. The Examiner alleges that claim 18 requires the indications to be "different", and therefore cannot see how a result "can be similar and different at the same time."

Applicants traverse the instant rejection and submit that the Examiner is misreading the plain language of claim 18 and reading in limitations which are not present in claim 18. Subparagraph b, last paragraph of claim 18 never required (now or prior to amendment) that the

indications of the first and second assays be different. Rather, it states that the indication of the second assay only (i.e., *not* as compared to the first assay) may vary depending on the menopausal status of the individual being tested, relative to the indication the second assay may provide in another or the same individual in a different menopausal state. Such variation is not measured relative to any indication by the first assay. Rather, it is measured relative to the various indications states the second assay is capable of providing.

Claim 31 clearly states that the indications from the first and second assay (whatever that second assay result might be, depending on the menopausal state) may either be the same, or "discernibly different." In claim 31, therefore, the indications from the first and second assays *are* being compared. The relationship between the indications from the first and second assay as defined in claim 31 is clear as written: if the indications from the first and second assay are not discernibly different, then they are similar. One of skill in the art would know how to detect whether or not certain indications had a "discernible" difference when comparing the indications, and ample guidance is given in the specification as to how one might do this (see, e.g., pages 8-10).

Therefore, the Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § U.S.C. §112¶2 for indefiniteness.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-832-1000.

Respectfully Submitted,

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